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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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09/839,643

04/20/2001

Gad Keren

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04/27/2010

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EXAMINER

NGUYEN, CAMTU TRAN

ART UNIT

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3772

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PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 09/839,643	<b>Applicant(s)</b> KEREN ET AL.	
	<b>Examiner</b> Camtu T. Nguyen	<b>Art Unit</b> 3772	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 22 January 2010.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 49-51, 59, 62, 68-70, 73, 78, 84, 86-89, 92 and 97-108 is/are pending in the application.
- 4a) Of the above claim(s) \_ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 59, 62, 68-70, 73 and 78 is/are allowed.
- 6) ☒ Claim(s) 49, 50, 85-87, 89, 97 and 102-105 is/are rejected.
- 7) ☒ Claim(s) 10, 51, 84, 88, 92, 98, 101 and 106-108 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |   |   |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)         | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____                                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)         | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____   | 6) <input type="checkbox"/> Other: _____                          |

## **DETAILED ACTION**

### ***Response to Amendment***

This Office Action is responding to applicant's amendment filed on 1/19/2010. Claims 49, 59, 69, 73, 78, 89, and 103 have been amended.

Applicant remarked that the Wilk reference does not teach the method for decreasing blood pressure in a heart chamber. Such remarks are persuasive, thus, the rejection associated with the Wilk reference regarding the method claims has been withdrawn.

Claim 59, as amended, now distinguished over Wilk & Bailey reference. Therefore, the rejection associated with these references regarding claim 55 have been withdrawn.

Applicant's remarks against the Bailey reference deemed persuasive. Thus, the rejection associated with the Bailey reference has been withdrawn.

The claims, as amended, have been carefully considered but deemed not allowable in view of the following rejection(s).

### ***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for

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patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 49-50, 86-89, 97, 102-103, and 105 are rejected under 35 U.S.C. 102(e) as being anticipated by Wolf et al (U.S. Patent Application Publication No. US 2002/0165606 A1).

Wolf et al discloses in Figures 2-4 & 7 a differential pressure regulating device comprising a shunt (12, 34) positioned in heart wall between two heart chambers or vessels to enable blood/fluids to flow therebetween (paragraph 0028), and an adjustable valve device (10) to regulate the blood/fluids.

Regarding claim 49 requiring the shunt between a left atrium & a right atrium of the heart, Wolf et al reference discloses the “chambers” are referred to the left & the right chambers (paragraph 0028 line 1-3) and the “heart wall” is referred to interatrial septum (paragraph 0029), as such, the Wolf et al’s shunt (12, 34) meets the limitations in claim 49.

Figure 1a illustration the shunt device is implanted between the left ventricle (LV) & coronary artery (CA), however, in view of Wolf et al's disclosure in paragraph 0028 lines 1-3, it is clearly that the shunt is implanted between the left atrium & the right atrium. Figure 1a also illustrates one end of shunt in LV while the opposing end in CA, it can be clearly perceived that one end of the shunt is implanted in the left atrium & the opposing end of the shunt is implanted in the right atrium.

Regarding claim 49 reciting the shunt **enabling blood flow between the left atrium & the right atrium and decreasing blood pressure in an atrium**, Wolf et al reference discloses the high-pressure blood flow causes valve (10) of shunt (12, 34) to open, allowing blood flow between the left atrium & the right atrium, thereby, decreasing blood pressure in one of the atria.

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The Wolf et al shunt (12, 34) would perform the method of decreasing blood pressure in a heart chamber.

Regarding claim 50, Figure 1a illustrates the shunt is anchored between the LV & CA, in view of the disclosure in Wolf et al, paragraph 0028 lines 1-3, it is clearly that the shunt is anchored through interatrial septum (paragraph 0029). Regarding the fixation elements, Figures 2-4 illustrates flared ends of the shunt anchored the shunt therethrough.

Regarding claim 86, see rejection to claims 49 & 51 above.

Regarding claim 87, see rejection to claim 51 above.

Regarding claim 89, see rejection to claim 51 above

Regarding claim 97 reciting a sensor, Wolf et al discloses a sensor (30) positioned within the shunt (12), the sensor (30) senses electrical signals produced in the heart muscle, a state of the heart, and causes the valve (12) to open in response to the reading of the sensor (30), see paragraph 0050.

Regarding claim 100, the valve (10) would open in response to a differential pressure between opposite ends of valve.

Regarding claim 102, Wolf et al discloses shunt (12) in implanted in interatrial septum (paragraph 0029), which is in a transseptal hole.

Regarding claim 103, Wolf et al shunt (12), presented above, discloses shunt (12) is configured for positioning within a septum between atria of the heart (paragraph 0028-0030), a sensor (30) senses the electrical signals produced in the heart muscle, an actuator (36) to control the shunt.

Regarding claim 105, Wolf et al's shunt (12) comprising a valve (10).

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claim 104 is rejected under 35 U.S.C. 103(a) as being unpatentable over Wolf et al (U.S. Patent Application Publication No. US 2002/0165606 A1) in view of Wilk (U.S. Patent No. 7,294,115).

Wolf et al discloses in Figures 2-4 & 7 a differential pressure regulating device comprising a shunt (12) comprising all of the elements as recited in these claims including a sensor but does not teach the sensor comprises a pressure sensor.

Wilk discloses in Figures 9a-9b a shunt/stent (900) having a sensor (904) incorporated therein, the sensor (904) comprises a pressure sensor (column 17 lines 12-26) transmitting a blood pressure during diastole & systole cycles.

Therefore, it is obvious to one skilled in the art utilize the pressure sensor (904) taught by Wilk in Wolf et al's shunt (12) as such would allow the blood pressure to be monitored.

***Allowable Subject Matter***

Claims 51, 84, 88, 92, 98-101 and 106-108 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

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Claims 59, 68-70, 73, 78 are allowable.

Claim 62 is, previously withdrawn from consideration as a result of a restriction requirement, requires all the limitations of an allowable claim. Pursuant to the procedures set forth in MPEP § 821.04(a), **the restriction requirement among inventions shown in Figures 1, 2, 4, and 5, as set forth in the Office action mailed on 10/16/2007, is hereby withdrawn** and claim 62 hereby rejoined and fully examined for patentability under 37 CFR 1.104. In view of the withdrawal of the restriction requirement, applicant(s) are advised that if any claim presented in a continuation or divisional application is anticipated by, or includes all the limitations of, a claim that is allowable in the present application, such claim may be subject to provisional statutory and/or nonstatutory double patenting rejections over the claims of the instant application. Once the restriction requirement is withdrawn, the provisions of 35 U.S.C. 121 are no longer applicable. See *In re Ziegler*, 443 F.2d 1211, 1215, 170 USPQ 129, 131-32 (CCPA 1971). See also MPEP § 804.01.

### ***Conclusion***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Camtu T. Nguyen whose telephone number is 571-272-4799. The examiner can normally be reached on (M-F) 8:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Patricia Bianco can be reached on 571-272-4940. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Camtu T. Nguyen/

Examiner, Art Unit 3772

/Tatyana Zalukaeva/

Supervisory Patent Examiner, Art Unit 3761